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PATENT
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PROCEDURE PURSUANT TO
37 CFR § 1.116



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Myles, et al.

Confirmation No.: 4870

Application No.: 10/817532

Group Art Unit: 1625

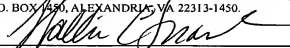
Filing Date: April 2, 2004

Examiner: N. Rahmani

For: **SYNTHETIC TECHNIQUES AND INTERMEDIATES FOR
POLYHYDROXY DIENYL LACTONES AND MIMICS THEREOF**

DATE OF DEPOSIT: August 31, 2007

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Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant respectfully requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. The review is requested for the reasons stated on the attached sheets. No more than five pages are provided.

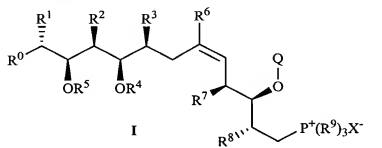
REMARKS

The present application provides intermediate compounds and improved methods of manufacture for the synthesis of discodermolide and/or its analogs. Recent findings indicate that compounds in this class surprisingly arrest cell development at the M phase by binding and stabilizing mitotic spindle microtubules, and thus resemble taxol in their mode of action-- in some cases, at much higher microtubule binding affinity. These results suggest that (+)-discodermolide and its analogs may hold considerable promise as anticancer agents.

Reconsideration of the present application in view of the remarks found hereinbelow is respectfully requested. Withdrawal of the Final Rejection is believed appropriate for the following reasons.

While the claimed invention includes a considerable number of individual molecules, the class is reasonably limited and claimed in clear and unambiguous language appreciated by all persons skilled in chemistry. The claims are also free of prior art. The only remaining rejection is under 35 U.S.C. § 112 ¶ 1. An exemplary claim is provided for your convenience.

23. A compound of the formula I:



wherein:

R^0 is C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, $(CH_2)_r(C_{3-6}$ cycloalkyl), $(CH_2)_r(aryl)$ or $(CH_2)_r(heterocycle)$, wherein r is selected from 0, 1, 2, 3, and 4;

R^1 , R^2 , R^3 , R^6 , R^7 and R^8 are independently H or C_{1-10} alkyl;

R^4 is an **acid labile hydroxyl protecting group**;

R^5 is an **oxidatively labile hydroxyl protecting group**;

each R^9 is independently C_{6-14} aryl;

Q is H or an **acid labile hydroxyl protecting group** wherein the hydroxyl protecting group has a mass of 135 Daltons or less and is unbranched at the atom bonded to the oxygen of the hydroxyl group being protected; and X is halogen.

The Examiner has alleged non-enablement submitting that the ordinarily skilled artisan would be unable to make and or use the invention commensurate in scope with the present claims without further support. Applicants submit this allegation is at odds with the totality of the relevant evidence and the test for enablement under the law.

Under MPEP § 2164.01, the test for enablement requires an analysis of whether the "disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed invention."

A patent need not teach, and **preferably omits**, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991, emphasis added herein). "The test of enablement is whether one reasonably skilled in the art could make or use the invention **from the disclosures in the patent coupled with information known in the art without undue experimentation.**" (*United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988, emphasis added herein)).

Claims 1 and 23 each use the same language ("**acid labile hydroxyl protecting group**" or "**oxidatively labile hydroxyl protecting group**") to define elements R⁴, R⁵, and Q. Applicants have provided definitions for each of the terms, including non-limiting preferred embodiments in the written description. Further, Applicants have incorporated by reference the textbook of Greene and Wuts, "*Protective Groups in Organic Synthesis*", 3rd edition, pp. 17-245 (John Wiley & Sons, New York, 1999) in the present application, for additional examples and teachings regarding their use (page 11, paragraphs [0028]-[0030]. For convenience during prosecution, Applicants further submitted parts of a second textbook by facsimile to the Examiner clearly showing the art (examples and teachings) known to one of ordinary skill at the time the invention was filed (Philip J. Kocienski, "*Protecting Groups*", 2nd Edition, pages 4-9 and 20-94. (2000)¹ Certain relevant portions from the Chapter 1 and

¹ Applicants specifically direct the Panel's attention to the type of language used in this textbook, such as for example, "protecting groups cleaved by acid" (i.e., acid-labile protecting groups) listed on the Contents page, in the Chapter 1 Overview at pages 4-6, and "protecting groups cleaved by oxidation" (i.e., oxidatively-labile protecting groups) listed on the Contents page, and in the Chapter 1 Overview at pages 8-9, clearly indicating

the Contents section of the latter cited textbook are included for your convenience on pages 5 and 6 of this document. Schemes have been omitted to save space but will be made available upon request.

MPEP § 2164.02 states that “[p]roof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation. Further, to make a “reasonable basis” rejection, the Examiner must take the disclosure as being in compliance with the requirements of 35 U.S.C. § 112 ¶ 1 unless there is a reason to doubt the objective truth of disclosure necessarily relied upon to support enablement. (see MPEP § 2164.04 and *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)). The aforementioned references clearly show that one of ordinary skill in the art would readily know the metes and bounds of the claimed terms at issue, and would be familiar with the chemistry relevant to the preparation of the claimed compounds. Accordingly, the ordinarily skilled artisan could make and use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

CONCLUSION

For at least the reasons stated above, Applicants submit that claims 1 to 23 are adequately enabled, and respectfully request that the rejection to Claims 1 to 23 under 35 U.S.C. § 112, first paragraph be withdrawn.

Date: August 31, 2007


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that the scope and type of protecting groups of this nature are understood and employed by one of ordinary skill in the art. Further examples are taught in Chapter 2 or Kocienski, entitled, “Hydroxyl Protecting Groups”.